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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,910	01/12/2006	Jonathan Alexander Terrett	2543-1-040PCT/US	1458

23565 7590 01/05/2010  
KLAUBER & JACKSON  
411 HACKENSACK AVENUE  
HACKENSACK, NJ 07601

EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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01/05/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,910	<b>Applicant(s)</b> TERRETT, JONATHAN ALEXANDER	
	<b>Examiner</b> ANNE L. HOLLERAN	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 10/10/2009 is acknowledged.

Claims 33-42 are pending and examined on the merits.

#### ***Claim Rejections Withdrawn:***

##### ***Claim Rejections - 35 USC § 112***

The rejection of claims 33-42 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detection of PTK7 polypeptides comprising or consisting of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for methods of detection of a PTK7 polypeptide that is a derivative having at least 70% identity to SEQ ID NO:1 or a fragment at least 100 amino acids in length having at least 70% homology over the length of the fragment to SEQ ID NO: 1, where the methods have the use of screening for and/or diagnosis or prognosis of carcinoma selected from breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject, and/or monitoring the effectiveness of carcinoma therapy is withdrawn in view of the amendments to the claims.

##### ***Claim Rejections - 35 USC § 102***

The rejection of claims 33-42 under 35 U.S.C. 102(e) as being anticipated by Hess-Stumpp (US 6,780,594; Aug. 24, 2004; effective filing date Oct. 26, 2000) is withdrawn in view of the amendment to the claims.

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***Claim Rejections Maintained and New Grounds of Rejection:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite because “the level of said polypeptide” lacks antecedent basis.

Suggested language is: “the detected or quantified polypeptide”.

Claims 35 and 38 are indefinite because they depend from claim 33, but refer to "a PTK7 polypeptide". This rejection would be obviated by amending to “said PTK7 polypeptide”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-42 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Mack (US 7,189,507; Mar. 13, 2007; effective filing date Apr. 12, 2002).

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Applicants' arguments have been carefully considered, but fail to persuade. Applicants state that Mack does not disclose or suggest a method of screening and/or diagnosis of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject as defined by the claims particularly as amended. Applicants further state that the presently claimed method of screening is directed to biological samples taken from the compartments where the carcinomas in object are suspected, and thus delimits and distinguishes from the teachings of Mack.

This is not persuasive because Mack teaches that samples from lung, kidney or bone, in addition to ovarian cancer tissue and for comparison purposes, may be used for detection of ovarian cancer-associated sequences (see column 20, lines 3-6; and lines 52-57). Claim 33 "comprises" the step of detecting and/or quantifying, in a biological sample selected from breast, pancreatic, lung, bladder, kidney or bone tissue obtained from the subject to be screened. Thus, claim 33 encompasses a method as taught by Mack where both ovarian cancer tissue and lung, kidney or bone tissues are used as samples for detecting and/or quantifying a PTK7 polypeptide as defined in the claims. Therefore, Mack teaches the methods as claimed.

Claims 33-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Gish (US PGPub 2007/0014801 A1; published Jan. 18, 2007; effective filing date Oct. 12, 2001).

Gish teaches detection of a protein sequence that is the same as that of SEQ ID NO: 1 (see alignment) in breast or lung tissue in addition to prostate cancer tissue, where the polypeptide level is compared to a control, and where the sample is contacted with a capture reagent that may be labeled. See alignment below, and page 11, paragraph 0110-0112;

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paragraph 0114; page 22, paragraph 0207; page 23, paragraph 0213-0215. Therefore, Gish

teaches

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; Publication No. US20070014801A1
; GENERAL INFORMATION:
; APPLICANT: Gish, Kurt C.
; APPLICANT: Mack, David H.
; APPLICANT: Wilson, Keith E.
; APPLICANT: Afar, Daniel
; APPLICANT: Peter, Hevezi
; TITLE OF INVENTION: Methods of Diagnosis of Prostate Cancer, Compositions and Methods
; TITLE OF INVENTION: of Screening for Modulators of Prostate Cancer
; FILE REFERENCE: 05882.0183.NPUS00
; CURRENT APPLICATION NUMBER: US/09/976,858
; CURRENT FILING DATE: 2001-10-12
; PRIOR APPLICATION NUMBER: 60/276,791
; PRIOR FILING DATE: 2001-03-16
; PRIOR APPLICATION NUMBER: 60/288,589
; PRIOR FILING DATE: 2001-05-04
; PRIOR APPLICATION NUMBER: 60/276,888
; PRIOR FILING DATE: 2001-03-16
; PRIOR APPLICATION NUMBER: 60/286,214
; PRIOR FILING DATE: 2001-04-24
; PRIOR APPLICATION NUMBER: 60/281,922
; PRIOR FILING DATE: 2001-04-06
; PRIOR APPLICATION NUMBER: 60/263,957
; PRIOR FILING DATE: 2001-01-24
; NUMBER OF SEQ ID NOS: 294
; SOFTWARE: PatentIn version 3.2
; SEQ ID NO 290
; LENGTH: 1070
; TYPE: PRT
; ORGANISM: human organism
US-09-976-858-290

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Query Match          100.0%; Score 5656; DB 3; Length 1070;
Best Local Similarity 100.0%;
Matches 1070; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy      1 MGAARGSPARPRRLPLLSVLLLP LLGGTQTAIVFIKQPSSQDALQGRRALLRCEVEAPGP 60
        |||
Db      1 MGAARGSPARPRRLPLLSVLLLP LLGGTQTAIVFIKQPSSQDALQGRRALLRCEVEAPGP 60
        |||

Qy      61 VHVVWLLDGAPVQDTERRFAGGSSLSFAAVDRLQDSGTFQCVARDDVTGEEARSANASFN 120
        |||
Db      61 VHVVWLLDGAPVQDTERRFAGGSSLSFAAVDRLQDSGTFQCVARDDVTGEEARSANASFN 120
        |||

Qy      121 IKWIEAGPVVLKHPASEABIQPQTQVTLRCHIDGHPRTYQWFRDGTPLSDGQSNHTVSS 180
        |||
Db      121 IKWIEAGPVVLKHPASEABIQPQTQVTLRCHIDGHPRTYQWFRDGTPLSDGQSNHTVSS 180
        |||

Qy      181 KERNLTLRPA GPEHSGLYSCCAHSAFGQACSSQNFTLSIADES FARVVLAPQDVVVARYE 240
        |||
Db      181 KERNLTLRPA GPEHSGLYSCCAHSAFGQACSSQNFTLSIADES FARVVLAPQDVVVARYE 240
        |||

Qy      241 EAMFHCQFSAQPPPSLQWLFEDETPITNRSRPPHLRRATVVFANGSLLLTQVRPRNAGIYR 300
        |||
Db      241 EAMFHCQFSAQPPPSLQWLFEDETPITNRSRPPHLRRATVVFANGSLLLTQVRPRNAGIYR 300
        |||

Qy      301 CIGQGQRGPPPIILEATLHLAEIEDMPLFEPRVFTAGSEERVTC LPPKGLPEPSVWWEHAG 360
        |||
Db      301 CIGQGQRGPPPIILEATLHLAEIEDMPLFEPRVFTAGSEERVTC LPPKGLPEPSVWWEHAG 360
        |||

Qy      361 VRLPTHGRVYQKGHELVLANIAESDAGVYTCHAA NLAGQRRQDVNITVATVPSWLKKPQD 420
        |||
Db      361 VRLPTHGRVYQKGHELVLANIAESDAGVYTCHAA NLAGQRRQDVNITVATVPSWLKKPQD 420
        |||

Qy      421 SQLEEGKPGYLDCLTQATPKPTVVWYRNQMLISEDSRFEVFKNGTLRINSVEVYDGTWYR 480
        |||
Db      421 SQLEEGKPGYLDCLTQATPKPTVVWYRNQMLISEDSRFEVFKNGTLRINSVEVYDGTWYR 480
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Qy      481 CMSSTPAGSIEAQARVQVLEK LKFTPPPQPPQCM EFDKEATVPCSATGREKPTIKWERAD 540
        |||

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Db      481  CMSSTPAGSIEAQARVQVLEKLFKFTPPPQPQQCMFEFDKEATVPCSATGREKPTIKWERAD  540
Qy      541  GSSLPEWVTDNAGTLHFARVTRDDAGNYTCIASNGPQQQIRAHVQLTVAVFITFKVEPER  600
        |||
Db      541  GSSLPEWVTDNAGTLHFARVTRDDAGNYTCIASNGPQQQIRAHVQLTVAVFITFKVEPER  600
Qy      601  TTVYQGHTALLQCEAQGDPKPLIQWKGKDRILDPTKLGPRMHIFQNGSLVIHDEVAPEDSG  660
        |||
Db      601  TTVYQGHTALLQCEAQGDPKPLIQWKGKDRILDPTKLGPRMHIFQNGSLVIHDEVAPEDSG  660
Qy      661  RYTCIAGNSCNIKHTEAPLYVVDKVPVPEESEGPGSPPPYKMIQTIGLSVGAAYYIIAVL  720
        |||
Db      661  RYTCIAGNSCNIKHTEAPLYVVDKVPVPEESEGPGSPPPYKMIQTIGLSVGAAYYIIAVL  720
Qy      721  GLMFYCKKRCKAKRLQKQPEGEEPEMECLNGGPLQNGQPSAEIQEEVALTSLGSGPAATN  780
        |||
Db      721  GLMFYCKKRCKAKRLQKQPEGEEPEMECLNGGPLQNGQPSAEIQEEVALTSLGSGPAATN  780
Qy      781  KRHSTSDKMHFPRSSLQPIITTLGKSEFGEVFLAKAQGLEEGVAETLVLVKSLSQTKDEQQQ  840
        |||
Db      781  KRHSTSDKMHFPRSSLQPIITTLGKSEFGEVFLAKAQGLEEGVAETLVLVKSLSQTKDEQQQ  840
Qy      841  LDFRRELEMFGLNHNANVVRLLGLCREAEPHYMVLEYVDLGDLDKQFLRISKSKDEKLKSQ  900
        |||
Db      841  LDFRRELEMFGLNHNANVVRLLGLCREAEPHYMVLEYVDLGDLDKQFLRISKSKDEKLKSQ  900
Qy      901  PLSTKQKVALCTQVALGMEHLSNNRFVHKDLAARNCLVSAQRQVKVSALGLSKDVYNSEY  960
        |||
Db      901  PLSTKQKVALCTQVALGMEHLSNNRFVHKDLAARNCLVSAQRQVKVSALGLSKDVYNSEY  960
Qy      961  YHFRQAWVPLRWMSPEAILEGDFSTKSDVWAFGVLMMWEVFTHGEMPHGGQADDEVLADLQ  1020
        |||
Db      961  YHFRQAWVPLRWMSPEAILEGDFSTKSDVWAFGVLMMWEVFTHGEMPHGGQADDEVLADLQ  1020
Qy      1021 AGKARLPQPEGCPKLYRLMQRCWALSPKDRPSFSEIASALGDSTVDSP  1070
        |||
Db      1021 AGKARLPQPEGCPKLYRLMQRCWALSPKDRPSFSEIASALGDSTVDSP  1070

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### *Conclusion*

No claim is allowed. The disclosure of US20070059712 is cumulative to that of Gish (US 2007/0014801).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
December 31, 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643